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(54) Title: BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH CINNAMALDEHYDE

(57) Abstract: A pullulan-free edible film composition for oral cleansing, breath freshening, and anti-microbial benefits includes a film forming agent and cinnamaldehyde. In a treatment process, effective amounts of cinnamaldehyde is delivered to the oral cavity by the edible film for convenient oral cleansing and breath freshening benefits. A method of making the pullulan-free edible film composition includes forming an aqueous solution of film forming agents and cinnamaldehyde and drying the aqueous solution to form a dry edible film.

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## BREATH FRESHENING AND ORAL CLEANSING PRODUCT WITH CINNAMALDEHYDE

### RELATED U.S. APPLICATION

**[0001]** Priority is claimed to provisional patent application serial no. 60/319,346, filed June 25, 2002 and to provisional patent application serial no. 60/319,370, filed June 28, 2002.

### TECHNICAL FIELD

**[0002]** The present invention related, in general, to edible films and, more particularly, to pullulan-free edible film compositions containing cinnamaldehyde and to methods of making the film compositions.

### BACKGROUND

**[0003]** There is considerable consumer demand for products that freshen breath and kill bacteria in the mouth. An oral product with breath freshening and bactericidal benefits is a convenient delivery for oral cleansing in the oral cavity and freshening breath.

**[0004]** Of course, breath freshening is a very important part of everyday life. In order to facilitate proper oral hygiene, oral cleansing and breath freshening practices should be conducted repeatedly throughout the day.

**[0005]** However, oral cleansing and breath freshening may be difficult or inconvenient at times, depending on the nature of the breath freshening desired and the situation in which the breath freshening must occur. Brushing, flossing, cleaning your tongue and gargling using a variety of devices and compositions are common oral care practices well-suited for the privacy of one's home. But, such devices and compositions are less convenient to use away from the home where bathroom facilities might be scarce, unavailable or unsanitary.

[0006] It is known to incorporate active agents into oral products for the purpose of providing oral benefits including breath freshening and bactericidal properties. Such systems have the advantage of providing a rapid effect and convenient delivery.

## SUMMARY OF INVENTION

[0007] The present invention relates to methods of freshening breath and oral cleansing. Furthermore, the present invention relates to the composition of, and methods of producing an oral product. Specifically, the present invention relates to oral products intended bacterial and breath freshening properties. More specifically, the present invention relates to a dentifrice, chewing gum, confection, lozenge, mouthwash, mouth spray or edible film containing an effective amount of essential oils which produce a synergistic effect of bacterial properties for oral cleansing and breath freshening, by which the inventive composition effectively inactivates or kills oral bacteria and freshens breath through the consumption of the dentifrice, chewing gum, confection, lozenge, mouthwash, mouth spray or edible film product.

[0008] In an embodiment of the present invention, the oral product is chewing gum or any variation including but not limited to bubble gums, pellets, gum balls or sticks. Chewing gums may be coated or not coated and be of a variety of flavors, shapes and sizes.

[0009] In an embodiment of this invention, the oral product is a confectionery composition including but not limited to hard candy, chewing candy, filled candy and pressed tablets.

[0010] In another embodiment of the present invention, the oral product is a pullulan free edible film composition that includes an effective amount of a film forming agent, and an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cinnamaldehyde.

[0011] In yet another embodiment of the invention, a method of oral cleansing includes applying a pullulan-free edible film to the oral cavity, where the edible film includes an effective amount of a film forming agent, and an effective amount

of an antimicrobial agent where the antimicrobial agent comprises cinnamaldehyde.

[0012] In still another embodiment of the invention, a method of making a pullulan-free edible film includes forming an aqueous solution that includes a maltodextrin, a hydrocolloid, and a filler, adding an effective amount of an antimicrobial agent to the aqueous solution, where the antimicrobial agent comprises cinnamaldehyde, and drying the aqueous solution to form a dry edible film.

[0013] A further embodiment of the invention includes a treatment method for reducing the number or activity of bacteria in the oral cavity by providing an edible film composition including cinnamaldehyde in an amount sufficient to kill or deactivate oral bacteria, and causing a person in need of the treatment to consume the edible film composition, whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.

[0014] In another embodiment the oral product is a dentifrice.

#### DETAILED DESCRIPTION

[0015] It is known to use chewing gum, confections and thin films as a vehicle for delivering components to the oral cavity which provide oral benefits such as breath freshening and bactericidal properties. Such systems have the advantage of providing a consumer with a convenient and inexpensive method for maintaining oral health and fresh breath throughout the course of the day.

[0016] The present invention incorporates cinnamaldehyde as the active component for breath freshening and oral bactericidal benefits. Cinnamaldehyde is known to have bactericidal and anti-fungal properties.

[0017] In vitro tests were conducted with three subgingival plaque bacteria associated with oral malodor. The MIC (Minimum Inhibitory Concentrations) study protocol is as follows. Chlorhexidine was used as a positive control and sterile water was used as a negative control. Cinnamic aldehyde (cinnamaldehyde) was suspended in 10% methanol. Cinnamic aldehyde appeared as uniform suspension. Nine-six well microtiter plates were used for this study.

Each well contained  $5 \times 10^5$  colony forming units/ml of bacteria, serially diluted agents and bacterial growth medium. All bacterial cultures were incubated at 37°C and stationary. Bacterial growth was estimated spectrophotometrically at 660 nm, after 48 hours. The MIC for each test bacteria was defined as the minimum concentration of test compound limiting turbidity to < absorbance at 660 nm.

**[0018]** The MBC (Minimum bactericidal concentrations) were determined using the 96 well microtiter plate serial dilutions as described above for MIC studies. Serial dilution of cultures in wells showing no visible growth were performed and 10 microliters of culture were plated in triplicate on blood agar plates. Viable colonies were scored after incubation of the plates for 48 hours at 37°C. For each test bacterium, the number of CFU/ml were determined in the initial inoculum. The MBC was defined as the lowest concentration of a test compound that killed at least 99.9% of the cells present in the initial inoculum.

**[0019]** The results of the studies performed to obtain minimum inhibitory concentration (MIC) and minimum bactericidal concentration (MBC) of cinnamaldehyde are as follows. For *P. gingivalis*, the cinnamaldehyde had an MIC of 15.6 µg/ml and an MBC of 31.3 µg/ml. For *F. nucleatum* the cinnamaldehyde had an MIC of 15.6 µg/ml and an MBC of 31.3 µg/ml. Chlorhexidine was the positive control and produced an MIC and MBC of 1.25 µg/ml for both bacteria. The solvent of water with 10% methanol had no noticeable growth inhibitory effects on any of the three bacteria in the study.

**[0020]** The cinnamaldehyde used in the present invention is obtained from Northwestern Flavors, Inc at 120 N. Aurora Street, West Chicago, Illinois 60185, U.S.A.

**[0021]** In an embodiment, the invention comprises a treatment method for reducing the number or activity of bacteria in the oral cavity comprising the steps of providing an oral composition comprising cinnamaldehyde in an amount sufficient to kill or deactivate oral bacteria and causing a person in need of the treatment to consume the oral composition whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.

[0022] In an embodiment, the oral composition comprises additional breath freshening or oral health ingredients.

[0023] In an embodiment, the additional breath freshening or oral health ingredients comprise anti-microbial ingredients.

[0024] In an embodiment, the additional breath freshening or oral health ingredients comprise food acceptable salts of zinc or copper.

[0025] In an embodiment, the additional breath freshening or oral health ingredients comprise cooling agents.

[0026] In an embodiment, the additional breath freshening or oral health ingredients comprise pyrophosphate or polyphosphate.

[0027] In an embodiment, the oral composition is formulated to deliver at least 0.005% concentration of cinnamaldehyde to the oral cavity.

[0028] In an embodiment, the oral composition is formulated to deliver at least 0.01 % concentration of cinnamaldehyde to the oral cavity.

[0029] In an embodiment, the oral compositions is formulated to deliver at least 0.1% concentration of cinnamaldehyde to the oral cavity.

[0030] Given that cinnamaldehyde is a hydrophobic compound, there are several methods, which may be used to enhance the release of the cinnamaldehyde from the oral composition. In a chewing gum product, the gum base is hydrophilic which would facilitate the release of the cinnamaldehyde. In an oral composition, the cinnamaldehyde may be encapsulated, spray dried, formulated into the coating and combinations thereof.

[0031] In an embodiment of the present invention, an effective amount for anti-microbial benefit of cinnamaldehyde is present in a chewing gum formulation. In an embodiment of the present invention, the amount of cinnamaldehyde present is up to about 5% by weight of the chewing gum product. In an embodiment of the present invention, the amount of cinnamaldehyde is about 1% of the weight of the chewing gum product. In another embodiment, the cinnamaldehyde is present in the amount of about 0.25% by weight of the chewing gum product. In another embodiment, the cinnamaldehyde is present in the amount of about 0.01% by weight of the chewing gum product.

[0032] In general, a chewing gum composition typically comprises a waterbulk portion, a waterchewable grams base portion and typically waterflavoring agents. The waterportion dissipates with a portion of the flavoring agent over a period of time during chewing. The gum base portion is retained in the mouth throughout the chew.

[0033] The insoluble gum base generally comprises elastomers, resins, fats and oils, softeners and inorganic fillers. The gum base may or may not include wax. The insoluble gum base can constitute approximately 5% to about 95% by weight of the chewing gum, more commonly the gum base comprises 10% to about 50% of the gum, and in some preferred embodiments approximately 25% to about 35% by weight, of the chewing gum.

[0034] In a particular embodiment, the chewing gum base of the present invention contains about 20% to about 60% by weight synthetic elastomer, up to about 30% by weight natural elastomer, about 5% to about 55% by weight elastomer plasticizer, about 4% to about 35% by weight filler, about 5% to about 35% by weight softener, and optional minor amounts (about 1% or less by weight) of miscellaneous ingredients such as colorants, antioxidants, etc.

[0035] Synthetic elastomers may include, but are not limited to, polyisobutylene with GPC weight average molecular weight of about 10,000 to about 95,000, isobutylene-isoprene copolymer (butyl elastomer), styrenecopolymers having styrene-butadiene ratios of about 1:3 to about 3:1, polyvinyl acetate having GPC weight average molecular weight of about 2,000 to about 90,000, polyisoprene, polyethylene, vinyl acetate vinyl laurate copolymer having vinyl laurate content of about 5% to about 50% by weight of the copolymer, and combinations thereof.

[0036] Preferred ranges for polyisobutylene are 50,000 to 80,000 GPC weight average molecular weight and for styreneare 1:1 to 1:3 bound styrene for polyvinyl acetate are 10,000 to 65,000 GBC weight average molecular weight with the higher molecular weight polyvinyl acetates typically used in bubble gum base, and for vinyl acetatelaurate, vinyl laurate content of 10.

[0037] Natural elastomers may include natural rubber such as smoked or liquid latex and guayule as well as natural gums such as jelutong, lechi caspi, perillo, sorva, massaranduba balata, massaranduba chocolate, nispero, rosindinha, chicle, gutta hang kang, and combinations thereof. The preferred synthetic elastomer and natural elastomer concentrations vary depending on whether the chewing gum in which the base is used is adhesive or conventional, bubble gum or regular gum, as discussed below. Preferred natural elastomers include jelutong, chicle, sorva and massaranduba balata.

[0038] Elastomer plasticizers may include, but are not limited to, natural rosin esters such as glycerol esters or partially hydrogenated rosin, glycerol esters of polymerized rosin, glycerol esters of partially dimerized rosin, glycerol esters of rosin, pentaerythritol esters of partially hydrogenated rosin, methyl and partially hydrogenated methyl esters of rosin, pentaerythritol esters of rosin; synthetics such as terpene resins derived from alpha beta and/or any suitable combinations of the foregoing. The preferred elastomer plasticizers will also vary depending on the specific application, and on the type of elastomer which is used.

[0039] Fillers/texturizers may include magnesium and calcium carbonate, ground limestone, silicate types such as magnesium and aluminum silicate, clay, alumina, talc, titanium oxide, mono-, di- and tri-phosphate, cellulose polymers, such as wood, and combinations thereof.

[0040] Softeners /emulsifiers may include tallow, hydrogenated tallow, hydrogenated and partially hydrogenated vegetable oils, cocoa butter, glycerol monostearate, glycerol triacetate, lecithin, mono and triglycerides, acetylated monoglycerides, fatty acids (e.g. stearic, palmitic, oleic and linoleic acids), and combinations thereof.

[0041] Colorants and whiteners may include FD&C dyes and lakes, fruit and vegetable extracts, titanium dioxide, and combinations thereof.

[0042] The base may or may not include wax. An example of a wax gum base is disclosed in U.S. Patent No. 5,286,500, the disclosure of which is incorporated herein by reference.



**[0043]** In addition to a water insoluble gum base portion, a typical chewing gum composition includes a water soluble bulk portion and one or more flavoring agents. The water soluble portion can include bulk sweeteners, high intensity sweeteners, flavoring agents, softeners, emulsifiers, colors, acidulants, fillers, antioxidants, and other components that provide desired attributes.

**[0044]** Softeners are added to the chewing gum in order to optimize the chewability and mouthfeel of the gum. The softeners, which are also known as plasticizers and plasticizing agents, generally constitute between approximately 0.5% to about 15% by weight of the chewing gum. The softeners may include glycerin, lecithin, and combinations thereof. Aqueous sweetener solutions such as those containing sorbitol, hydrogenated starch hydrolysates, corn syrup and combinations thereof, may also be used as softeners and binding agents in chewing gum.

**[0045]** Bulk sweeteners include both sugar and sugarless components. Bulk sweeteners typically constitute about 5% to about 95% by weight of the chewing gum, more typically, about 20% to about 80% by weight, and more commonly, about 30% to about 60% by weight of the gum. Sugar sweeteners generally include saccharide components commonly known in the chewing gum art, including but not limited to, sucrose, dextrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup solids, and the like, alone or in combination. Sugarless sweeteners include, but are not limited to, sugar alcohols such as sorbitol, mannitol, xylitol, hydrogenated starch hydrolysates, maltitol, and the like, alone or in combination.

**[0046]** High intensity artificial sweeteners can also be used, alone or in combination, with the above. Preferred sweeteners include, but are not limited to, sucralose, aspartame, NAPM derivatives such as neotame, salts of acesulfame, alitame, saccharin and its salts, cyclamic acid and its salts, glycyrrhizinate, dihydrochalcones, thaumatin, monellin, and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Such techniques as wet granulation, wax granulation, spray

drying, spray chilling, fluid bed coating, coacervation, and fiber extension may be used to achieve the desired release characteristics.

**[0047]** Combinations of sugar and/or sugarless sweeteners may be used in chewing gum. Additionally, the softener may also provide additional sweetness such as with aqueous sugar or alditol solutions.

**[0048]** If a low calorie gum is desired, a low caloric bulking agent can be used. Examples of low caloric bulking agents include: polydextrose; Raftilose, Raftilin; Fructooligosaccharides (NutraFlora); Palatinose oligosaccharide; Guar Gum Hydrolysate (Sun Fiber); or indigestible dextrin (Fibersol). However, other low calorie bulking agents can be used.

**[0049]** A variety of flavoring agents can also be used, if desired. The flavor can be used in amounts of about 0.1 to about 15 weight percent of the gum, and preferably, about 0.2% to about 5% by weight. Flavoring agents may include essential oils, synthetic flavors or mixtures thereof including, but not limited to, oils derived from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oil, oil of wintergreen, anise and the like. Artificial flavoring agents and components may also be used. Natural and artificial flavoring agents may be combined in any sensorially acceptable fashion. Flavoring may include a cooling agent to enhance the flavor and perceived breath freshening of the product. Cooling agents include menthol, ethyl p-menthane carboxamide, N,2,3-trimethyl-2-isopryl-butanamide, menthyl glutarate FEMA 4006, menthyl succinate, menthol PG carbonate, menthol EG carbonate, menthyl lactate, menthone glyceryl ketal, menthol glyceryl ether, N-tertbutyl-p-menthane-3-carboxamide, p-menthane-3-carboxylic acid glycerol ester, methyl-2-isopryl-bicyclo (2.2.1), heptane-2-carboxamide, menthol methyl ether and combinations thereof.

**[0050]** In addition, to the active ingredients of the present invention, additional active ingredients or medicaments may be added for various purposes. If the medicament or active is water soluble in the chewing gum, it preferably will include a base/emulsifier system which leads to the desired concentration of the medicament in the saliva (more hydrophilic balance). If the medicament or active

is water insoluble, the chewing gum preferably includes a base/emulsifier system which leads to the desired concentration of the medicament in the saliva (more lipophilic balance).

**[0051]** In manufacturing the chewing gum including the active agent or ingredient, the active agent or medicament is added, preferably, early on in the mix. The smaller the amount of active ingredient used, the more necessary it becomes to preblend that particular ingredient to assume uniform distribution throughout the batch of gum. Whether a preblend is used or not, the active agent or medicament should be added within the first five minutes of mixing. For faster release, the active agent may be added late in the process.

**[0052]** Optionally, the chewing gum of the present invention may include additional breath freshening, anti microbial or oral health ingredients. Food acceptable metallic salts selected from zinc and copper salts of gluconic acid, zinc and copper salts of lactic acid, zinc and copper salts of acetic acid, zinc and copper salts of citric acid and combinations thereof.

**[0053]** Anti-microbial essential oils and flavor components such as peppermint, methyl salicylate, thymol, eucalyptol, cinnamic aldehyde, polyphosphate, pyrophosphate and combinations thereof.

**[0054]** Dental health ingredients such as fluoride salts, phosphate salts, proteolytic enzymes, lipids, anti-microbials, calcium, electrolytes, protein additives, dental abrasives and combinations thereof.

**[0055]** In general, chewing gum is manufactured by sequentially adding the various chewing gum ingredients to a commercially available mixer known in the art. After the ingredients have been thoroughly mixed, the gum mass is discharged from the mixer and shaped into the desired form such as rolling sheets and cutting into sticks, extruding into chunks or casting into pellets, which are then coated or panned.

**[0056]** Generally, the ingredients are mixed by first melting the gum base and adding it to the running mixer. The base may also be melted in the mixer itself. Color or emulsifiers may also be added at this time. A softener such as glycerin may also be added at this time, along with syrup and a portion of the bulking

agent. Further parts of the bulking agent are added to the mixer. Flavoring agents are typically added with the final portion of the bulking agent. Other optional ingredients are added to the batch in a typical fashion, well known to those of ordinary skill in the art.

[0057] The entire mixing procedure typically takes from five to fifteen minutes, but longer mixing times may sometimes be required. Those skilled in the art will recognize that many variations of the above described procedure may be followed.

[0058] Chewing gum base and chewing gum product have been manufactured conventionally using separate mixers, different mixing technologies and, often, at different factories. One reason for this is that the optimum conditions for manufacturing gum base, and for manufacturing chewing gum from gum base and other ingredients such as sweeteners and flavors, are so different that it has been impractical to integrate both tasks. Chewing gum base manufacture, on the one hand, involves the dispersive (often high shear) mixing of difficult-to-blend ingredients such as elastomer, filler, elastomer plasticizer, base softeners/emulsifiers and sometimes wax, and typically requires long mixing times. Chewing gum product manufacture, on the other hand, involves combining the gum base with more delicate ingredients such as product softeners, bulk sweeteners, high intensity sweeteners and flavoring agents using distributive (generally lower shear) mixing, for shorter periods.

[0059] The following are examples of formulations of cinnamaldehyde in chewing gum. The examples are not intended to exclude other variations in formulations and the present invention is not limited to these formulations.

Table 1. Antimicrobial Gum Formulas (% weight)

Ingredient	Example 1	Example 2	Example 3	Example 4	Example 5
Gum Base	26.00	26.00	26.00	27.5	27.5
Talc powder	3.00	3.00	3.00	3.00	3.00
Glycerine	0.50	0.50	0.50	0.50	0.50
Sorbitol	49.71	50.96	48.71	48.71	44.71
Glycerol	15.01	15.01	15.01	15.01	15.01
Mannitol	1.52	1.52	1.52	1.52	1.52
Maltitol	0.76	0.76	0.76	0.76	0.76
Water	1.18	1.18	1.18	1.18	1.18
Aspartame	0.53	0.53	0.53	0.53	0.53
Color	0.01	0.01	0.01	0.01	0.01
Zein	0.04	0.04	0.04	0.04	0.04
NaOH	0.01	0.01	0.01	0.01	0.01
Acesulphame Potassium	0.13	0.13	0.13	0.13	0.13
Cinnamic Aldehyde	1.50	0.25	2.50	1.00	5.00
Hydroxy-propylmethyl-cellulose	0.10	0.10	0.10	0.10	0.10
Total %	100.00	100.00	100.00	100.00	100.00

Table 2. Antimicrobial Gum Formulas (% weight)

Ingredient	Example 6	Example 7	Example 8	Example 9	Example 10
Gum Base	19.46	20.71	19.46	19.46	18.46
Sugar	62.13	62.13	61.13	62.63	61.63
Corn Syrup	15.57	15.57	15.57	15.57	13.57
Color	0.67	0.67	0.67	0.67	0.67
P.A.	0.67	0.67	0.67	0.67	0.67
Cinnamic Aldehyde	1.50	0.25	2.50	1.00	5.00
Total %	100.00	100.00	100.00	100.00	100.00

**[0060]** In an embodiment of the present invention, an effective amount for anti-microbial benefit of cinnamaldehyde is present in an edible film formulation. In an embodiment of the present invention, the amount of cinnamaldehyde present is up to 20% by weight of the edible film formulation. In an embodiment of the present invention, the amount of cinnamaldehyde is about 8% of the weight of the edible film product. In another embodiment, the cinnamaldehyde is present in the amount of about 5% by weight of the edible film product. Considering the

potency of cinnamaldehyde as described in the in vitro studies above, about 1% by weight of the edible film product may also be effective in bactericidal properties. In an embodiment, the amount of cinnamaldehyde present is in an amount above 21%. In an embodiment, the amount of cinnamaldehyde is present is in amount above 5%. In an embodiment, the amount of cinnamaldehyde present in an amount between 6% and 25%.

**[0061]** The present invention provides edible film formulations for oral mucoadhesion and methods of using and making same. In particular, the edible films of the present invention include at least three types of film forming agents other than pullulan.

**[0062]** Applicants have uniquely discovered that the use of a mixture of at least three types of film forming agents, such as maltodextrins, fillers (e.g., microcrystalline cellulose (MCC)) and hydrocolloids (e.g., sodium alginate), can be effectively utilized to prepare stand alone edible films. The edible films are composed of ingredients that are readily available, can be prepared at lower costs and display similar properties as compared to edible films composed of pullulan. In this regard, the edible films can provide a physiologically acceptable film, which is suitably adapted to adhere to oral surfaces of an oral cavity and rapidly dissolve therein.

**[0063]** The edible films of the present invention can be utilized to deliver or release oral care agent(s). Such agents include, anti-microbial agents and salivary stimulants to treat, for example, halitosis, dental plaque, gingivitis, xerostomia, dry mouth, like oral conditions or combinations thereof. Further, the oral care edible film can act as a breath freshener effective against malodor.

**[0064]** The oral cleansing and breath freshening effects of the edible film of the present invention can be achieved by entrapping the oral care agents within the oral cavity to provide extended efficacy. In this regard, the highly dissolvable edible film can act as a medium through which a pharmaceutically active oral agent can be administered via a mucous membrane of the oral cavity.

**[0065]** Further, the edible films can include a variety of other suitable ingredients, such as softeners, colorants, flavoring agents, emulsifiers, surfactants,

thickening agents, binding agents, sweeteners, fragrances, other like ingredients or combinations thereof.

**[0066]** In an embodiment, the edible films preferably include a mixture of at least three types of film forming agents, such as maltodextrins, fillers and hydrocolloids. It should be appreciated that the edible film of the present invention can be composed of one or more different compounds associated with each of the at least three types of film forming agents.

**[0067]** In an embodiment, the maltodextrin component constitutes between about 5% to about 60% by dry weight of the edible film, preferably about 20% to about 40% by dry weight. The maltodextrin component can be processed in any suitable way.

**[0068]** The hydrocolloid can provide thickness and decrease brittleness of the edible films. The hydrocolloid can include any suitable type, amount and number of hydrocolloids. In an embodiment, the hydrocolloid can constitute between about 10% to about 50% by dry weight of the edible film, preferably about 20% to about 30% by dry weight. The hydrocolloid can be derived from, for example, natural seaweeds, natural seed gum, natural plant exudates, natural fiber extracts, biosynthetic gums, gelatins, biosynthetic process starch or cellulosic materials, alginates, sodium alginate, calcium alginate, carrageenans, guar gum, locust gum, tara gum, gum arabic, ghatti gum, agar gum, xanthan gum, pectin, other like hydrocolloid source material or combinations thereof.

**[0069]** Any suitable food-grade bulk filler can also be added to the edible film. This can reduce any slimy texture as well as provide structure to the film thereby making it more palatable. In an embodiment, the filler can constitute about 5% to about 30% by dry weight of the film, preferably about 15% to about 25% by dry weight. The filler can include, for example, microcrystalline cellulose, cellulose polymers, such as wood, magnesium and calcium carbonate, ground limestone, silicates, such as magnesium and aluminum silicate, clay, talc, titanium dioxide, mono-calcium phosphate, di-calcium phosphate, tri-calcium phosphate, other like bulk fillers or combinations thereof.

**[0070]** It is believed that the unique mixture of at least three film forming agents other than pullulan, for example, a maltodextrin, a hydrocolloid and a bulk filler, can provide a stand alone edible film composition which exhibits many of the same desirable properties exhibited by more expensive pullulan-based edible film. Applicants have desirably discovered that the pullulan-free edible film formulation of the present invention can exhibit, for example, clean mouth feel, clean favor and ease of manufacture similar to currently available pullulan-based films.

**[0071]** As previously discussed, a variety of other suitable ingredients can be added to the edible film of the present invention. For example, any suitable medicament for oral cleansing, breath freshening or the like can be added to the film formulation. The medicaments can include, for example, a pH control agent, such as urea and buffers, inorganic components for tartar or caries control, such as phosphates and fluorides, a breath freshening agent such as zinc gluconate, an anti-plaque/anti-gingivitis agent, such as chlorhexidine, CPC, and triclosan, a saliva stimulating agent including, for example, food acids such as citric, lactic, maleic, succinic, ascorbic, adipic, fumaric and tartaric acids, a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral, other like medicaments or combinations thereof.

**[0072]** The medicaments can be delivered or released into the oral cavity for effective oral treatment, such as oral cleansing and/or breath freshening. In this regard, the film forming agent of the edible film can act to entrap the medicaments within the oral cavity thereby providing extended efficacy thereof. In doing so, it is believed that the pullulan free edible film compositions of the present invention more uniformly release the medicament into the oral cavity for absorption via open wounds or mucous membrane in a greater manner than could be previously achieved. Moreover, it is also believed that the mixture of film forming agents of the present invention can entrap the medicament within the oral cavity for an extended period of time to prolong and enhance the effects of the medicament. In addition, by extending the contact time of the medicament within the oral cavity,



the medicament is absorbed to a greater extent thereby increasing its bioavailability.

**[0073]** If reduced levels of film forming agents are utilized, softeners can be used to reduce the brittleness of the resulting films. The softeners, which are also known as plasticizers or plasticizing agents, generally constitute between about up to 20% by dry weight of the film, preferably about 2% to about 10% by dry weight. The softeners can include plasticizers containing, for example, sorbitol and other polyols, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrups, other like material or combinations thereof.

**[0074]** The edible film formulations of the present invention can also include colorants or coloring agents which can be used in any suitable amount to produce the desired color. Coloring agents can include, for example, natural food colors and dyes suitable for food, drug and cosmetic applications. The colorants are typically known as FD&C dyes and lakes.

**[0075]** A variety of flavoring agents can also be added to the edible films. Any suitable amount and type of artificial and/or natural flavoring agents can be used in any sensorially acceptable fashion. For example, the flavor can constitute about 0.1% to about 20% by dry weight of the film, preferably about 10% to 15%. The flavoring agent can include, for example, essential oils, synthetic flavors or mixtures including but not limited to oils delivered from plants and fruits such as citrus oils, fruit essences, peppermint oil, spearmint oil, other mint oils, clove oils, oil of wintergreen, anise and the like, flavor oils with germ killing properties such as menthol, eucalyptol, thymol, like flavoring agents or combinations thereof.

**[0076]** The flavor can be enhanced and evenly distributed throughout the product by emulsification. Any suitable amount and type of natural and/or synthetic food-grade emulsifier can be used. For example, the emulsifier can include lecithin, food-grade non-ionic emulsifiers, such as fatty acids ( $C_{10}$ - $C_{18}$ ), mono and diacyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propylene glycol, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristerate, enzyme modified lecithin, hydroxylated lecithins, other like emulsifiers or combinations thereof.

**[0077]** The flavors can be emulsified by any suitable emulsification process, such as mechanical processing, vigorous stirring, intense pressure fluctuations that occur in turbulent flow such as homogenization, sonication, colloid milling and the like.

**[0078]** The present invention provides methods of producing the edible film formulations. In general, the edible film formulations are prepared by forming a base solution that includes at least three types of film forming agents, such as maltodextrins, hydrocolloids and fillers and processing the base solution to form an edible film. Typically, the base solution is prepared by adding an initial mixture of dry ingredients to water that is stirred.

**[0079]** To the base solution, additional ingredients, such as flavor/emulsifier blends, sweeteners, softeners, color, the like or combinations thereof, can be added. In an embodiment, the solution is stirred continuously and heated at a temperature ranging from about 40°C to about 60°C. The solution then can be dried in any suitable manner, thereby, forming the edible film.

**[0080]** It should be appreciated that any suitable type, number and arrangement of process procedures or steps (i.e. mixing, heating, drying, cooling, addition of ingredients), process parameters (i.e. temperature, pressure, pH, process times) or the like can be utilized.

**[0081]** By way of example and not limitation, the following examples illustrate various embodiments of the edible film formulations of the present invention.

Table 3. Antimicrobial Thin Film Formulas (% by weight and dry basis)

Ingredient	Example 11	Example 12	Example 13	Example 14	Example 15
Water	11.00	10.00	10.00	10.00	10.00
Maltodextrin	26.00	23.23	24.56	25.96	23.00
Sodium Alginate	28.79	26.33	21.67	24.32	21.70
Carageenan	8.66	8.51	9.26	7.73	6.54
Microcrystalline Cellulose	8.75	7.02	9.12	9.56	6.58
Hydroxylated Lecithin	2.12	1.86	2.11	3.01	5.50
Glycerin	7.35	6.92	8.33	6.56	6.79
Menthol	2.40	-	-	1.05	-
Sucralose	3.13	3.08	4.42	-	-
High Intensity Sweetener	-	-	-	1.76	1.98
Cinnamic Aldehyde	1.75	12.00	10.48	10.00	17.15
Color	0.05	0.05	0.05	0.05	0.76
Total %	100.00	100.00	100.00	100.00	100.00

Table 4. Antimicrobial Edible Film Formulations (% by weight)

Ingredient	Example 16	Example 17	Example 18	Example 19	Example 20
Maltodextrin	25.05	47.00	31.20	36.80	21.00
Sodium Alginate	22.50	-	19.00	-	12.00
Calcium Alginate	-	15.15	-	11.45	-
Carageenan	-	-	-	-	12.00
Microcrystalline Cellulose	25.75	9.00	18.80	13.00	20.00
Calcium Carbonate	-	2.45	-	-	-
Glycerin	12.25	10.00	8.00	-	9.5
Sorbitol	-	-	-	6.00	1.55
Propylene Glycol	-	-	3.65	5.00	-
Menthol	1.00	0.05	-	1.25	-
Eucalyptol	-	0.05	-	1.00	-
Maleic Acid	-	-	-	-	1.35
Citric Acid	-	-	1.25	-	1.00
Chlorohexidene	1.85	-	-	1.00	-
Triclosan	-	1.25	-	1.00	-
Flavor	9.40	11.00	12.00	14.00	10.00
High Intensity Sweetener	1.25	1.00	1.05	1.45	1.50
Cinnamaldehyde	1.00	3.00	5.00	8.00	10.0
Color	0.05	0.05	0.05	0.05	0.10
Total %	100.00	100.00	100.00	100.00	100.00

Table 5. Antimicrobial Edible Film Formulations (% by weight)

Ingredient	Example 21	Example 22	Example 23	Example 24	Example 25
Maltodextrin	35.00	30.35	28.15	25.00	30.00
Sodium Alginate	22.15	19.10	17.00	28.15	-
Carageenan	-	-	-	-	20.15
Microcrystalline Cellulose	20.00	18.00	17.00	17.00	18.00
Gum Arabic	-	-	11.00	-	-
Glycerin	7.30	15.00	7.30	7.30	7.30
Flavor	11.00	11.00	11.00	11.00	11.00
Lecithin	2.00	2.00	2.00	2.00	2.00
High Intensity Sweetener	1.50	1.50	1.50	1.50	1.50
Cinnamaldehyde	1.00	3.00	5.00	8.00	10.0
Color	0.05	0.05	0.05	0.05	0.05
Total %	100.00	100.00	100.00	100.00	100.00

**[0082]** In yet another embodiment of the present invention, and effective amount for anti-microbial benefit of cinnamaldehyde is present in a confectionery formulation. In an embodiment of the present invention, the amount of cinnamaldehyde is present in an amount up to 3% by weight of the confectionery product. In an embodiment of the present invention, the amount of cinnamaldehyde is about 1% of the weight of the confectionery product. In another embodiment, the cinnamaldehyde is present in the amount of about 0.01% by weight of the confectionery product. Considering the potency of cinnamaldehyde as described in the in vitro studies above, 0.005% by weight of the confectionery product is also effective in bactericidal properties.

**[0083]** Confectionery products for this invention may be hard candies, chewy candies, coated chewy center candies and tabletted candies. By way of example, the hard candy is primarily comprised of corn syrup and sugar, and derives its name from the fact that it contains only 1.0% and 4% moisture. In appearance, these types of candies are solid, but they are actually supercooled liquids, which are far below their melting points. There are different types of hard candies.

Glass types are usually clear or made opaque with dyes; and Grained Types, which are always opaque.

**[0084]** The continuous making process of the Deposited Glass Types, with a sugar base are as follows. Corn syrup is spread over a cylinder heated by high pressure steam. Rapid heat exchange causes the water in the syrup to evaporate. The cooked syrup is discharged, colors and flavors are added. The syrup is cooled and deposited onto a stainless steel conveyor. These can be conveyed directly to hoppers which then discharge directly into molds.

**[0085]** The candy is conveyed to batch rollers, which shapes and sizes the batch. The candy enters a former, which shapes the individual pieces into discs, balls, barrels, etc. The present invention can be made into any shape, circles, squares, triangles etc., also into animal shapes or any other novelty molding available. The candy is then cooled, wrapped and packaged.

**[0086]** For Grained Types of candy, water and sugar are the basic components being mixed with other ingredients, and cooked at high temperatures (290°F-310°F), causing the water to turn to steam. The product is transferred to a cooling wheel, where it is collected in about 150 pound batches, placed in a pulling machine to aerate the product, and the flavor is added.

**[0087]** The candy is transferred to batch rollers where it is shaped and sized. The candy then enters a former, which shapes the individual pieces. The candy is cooled at a relative humidity of 35% and enters a rotating drum where it is coated with a fine sugar. The candy is then conveyed to the graining room for four hours at 90°F and 60% humidity. The entrapped air and moisture causes the product to grain.

**[0088]** The present invention can be of a variety of shapes, flavors and sizes. The present invention may contain sugar or may be sugarless.

**[0089]** Flavors used in the present invention may be peppermint oils, citrus oils, arvensis, fruit flavors, spearmint oils and the like.

**[0090]** Colors used in the present invention are colorants are typically known as FD&C dyes and lakes.

[0091] By way of example and not limitation, the following examples illustrate various embodiments of the confectionery formulations of the present invention.

Table 6. Antimicrobial Candy Formulations (% by weight)

Ingredient	Example 26	Example 27	Example 28	Example 29	Example 30
Corn Syrup	44.51	43.25	-	-	48.00
Sugar	53.49	50.00	-	-	47.00
Polyalcohols	-	-	95.20	95.77	-
Flavor	1.00	5.00	3.00	2.00	2.50
Color	0.50	1.00	0.60	0.80	0.50
Cinnamaldehyde	0.50	0.75	1.00	1.23	2.00
High Intensity Sweetener	-	-	0.20	0.20	-
Total %	100.00	100.00	100.00	100.00	100.00

## CLAIMS

1. A pullulan free edible film composition comprising:
  - (a) an effective amount of a film forming agent; and
  - (b) an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cinnamaldehyde.
2. The composition of claim 1 wherein the film forming agent comprises a mixture of a maltodextrine, a filler, and a hydrocolloid.
3. The composition of claim 2 wherein the maltodextrine comprises about 5 wt.% to about 60 wt.% of the edible film.
4. The composition of claim 2 wherein the maltodextrine comprises about 20 wt.% to about 40 wt.% of the edible film.
5. The composition of claim 2 wherein the hydrocolloid comprises about 10 wt.% to about 50 wt.% of the edible film.
6. The composition of claim 2 wherein the hydrocolloid comprises about 20 wt.% to about 30 wt.% of the edible film.
7. The composition of claim 2 wherein the filler comprises about 5 wt.% to about 30 wt.% of the edible film.
8. The composition of claim 2 wherein the filler comprises about 15 wt.% to about 25 wt.% of the edible film.
9. The composition of claim 2 wherein the hydrocolloid comprises a material selected from the group consisting of a natural gum, a biosynthetic gum, a natural seaweed, a natural plant extrudate, a natural fiber extract, a gelatin, a



biosynthetic process starch, a cellulosic material, an alginate, pectin, and combinations thereof.

10. The composition of claim 9 wherein the natural gum comprises a gum selected from the group consisting of natural seed gum, guar gum, locust gum, tara gum, gum arabic, ghatti gum, agar gum, and xanthan gum.

11. The composition of claim 9 wherein the alginate comprises sodium alginate or calcium alginate.

12. The composition of claim 9 wherein the natural seaweed comprises a carrageenan.

13. The composition of claim 2 wherein the filler comprises a food-grade bulk filler selected from the group consisting of microcrystalline cellulose, a cellulose polymer, magnesium carbonate, calcium carbonate, ground limestone, a silicate, clay, talc, titanium dioxide, a calcium phosphate, and combinations thereof.

14. The composition of claim 13 wherein the cellulose polymer comprises wood.

15. The composition of claim 13 wherein the silicate comprises magnesium or aluminum silicate.

16. The composition of claim 13 wherein the calcium phosphate comprises mono-calcium phosphate, di-calcium phosphate, or tri-calcium phosphate.

17. The composition of claim 1 wherein the cinnamaldehyde comprises at about 1 wt.% to about 25 wt.% of the edible film.

18. The composition of claim 1 wherein the cinnamaldehyde comprises about 6 wt.% to about 25 wt.% of the edible film.

19. The composition of claim 1 wherein the concentration of cinnamaldehyde comprises one of about 5 wt.%, about 8 wt.%, less than about 20 wt.%, and above about 21 wt.% of the edible film.

20. The composition of claim 1 wherein the composition of claim 1 wherein the concentration of cinnamaldehyde comprises above about 1 wt. % of the edible film.

21. The composition of claim 1 further comprising an effective amount of a medicament.

22. The composition of claim 21 wherein the medicament comprises an oral cleansing or breath freshening compound selected from the group consisting of a pH control agent, inorganic components for tartar or caries control, a breath freshening agent, an anti-plaque/anti-gingivitis agent, a saliva stimulating agent, a pharmaceutical agent, a nutraceutical agent, a vitamin, a mineral, and combinations thereof.

23. The composition of claim 22 wherein the pH control agent comprises urea.

24. The composition of claim 22 wherein the inorganic components for tartar or caries control comprise phosphates or fluorides.

25. The composition of claim 22 wherein the breath freshening agent agent comprises zinc gluconate.

26. The composition of claim 22 wherein the anti-plaque/anti-gingivitis agent comprises chlorhexidene, CPC, or triclosan.

27. The composition of claim 22 wherein the saliva stimulating agent comprises a food acid.

28. The composition of claim 27 wherein the food acid comprises an acid selected from the group consisting of citric, lactic, maleic, succinic, ascorbic, adipic, fumaric, and tartaric acids.

29. The composition of claim 1 further comprising an effective amount of a softening agent.

30. The composition of claim 29 wherein the softening agent comprises about 0 wt% to about 20 wt % of the edible film.

31. The composition of claim 29 wherein the softening agent comprises about 2 wt% to about 10 wt% of the edible film.

32. The composition of claim 29 wherein the softening agent comprises a plasticizer including a compound selected from the group consisting of sorbitol, glycerin, polyethylene glycol, propylene glycol, hydrogenated starch hydrolysates, corn syrup, and combinations thereof.

33. The composition of claim 1 further comprising an effective amount of a coloring agent.

34. The composition of claim 1 further comprising an effective amount of a flavoring agent.

35. The composition of claim 34 wherein the flavoring agent comprises about 0.1 wt% to about 20 wt % of the edible film.

36. The composition of claim 34 wherein the flavoring agent comprises about 10 wt% to about 15 wt% of the edible film.

37. The composition of claim 34 wherein the flavoring agent comprises a material selected from the group consisting of essential oils, synthetic flavors, fruit essences, anise, flavor oils with germ killing properties, and mixtures thereof.

38. The composition of claim 37 wherein the essential oils comprises citrus oil, peppermint oil, spearmint oil, mint oil, clove oil, oil of wintergreen.

39. The composition of claim 37 wherein the flavor oils with germ killing properties comprise menthol, eucalyptol, thymol, and combinations thereof.

40. The composition of claim 1 further comprising an effective amount of an emulsifying agent.

41. The composition of claim 40 wherein the emulsifying agent comprises lecithin, (C<sub>10</sub>-C<sub>18</sub>) fatty acids, mono and diacyl glycerides, ox bile extract, polyglycerol esters, polyethylene sorbitan esters, propylene glycol, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, enzyme modified lecithin, hydroxylated lecithins, and combinations thereof.

42. A method of oral cleansing by applying a pullulan-free edible film to the oral cavity, wherein the edible film comprises:

- (a) an effective amount of a film forming agent; and
- (b) an effective amount of an antimicrobial agent wherein the antimicrobial agent comprises cinnamaldehyde.

43. The method of claim 42 wherein the cinnamaldehyde comprises at least about 1 wt% of the edible film.

44. The method of claim 42 wherein the cinnamaldehyde comprises about 6 wt.% to about 25 wt.% of the edible film.

45. The method of claim 42 wherein the cinnamaldehyde concentration comprises one of about 5 wt.%, about 8 wt.%, less than about 20 wt.%, and above about 21 wt.% of the edible film.

46. The method of claim 42 wherein the film forming agent comprises a mixture of a maltodextrine, a filler, and a hydrocolloid.

47. The method of claim 46 wherein the maltodextrine comprises about 5 wt.% to about 60 wt.% of the edible film.

48. The method of claim 46 wherein the hydrocolloid comprises about 10 wt.% to about 50 wt.% of the edible film.

49. The method of claim 46 wherein the filler comprises about 5 wt.% to about 30 wt.% of the edible film.

50. The method of claim 46 wherein the hydrocolloid comprises a material selected from the group consisting of a natural gum, a biosynthetic gum, a natural seaweed, a natural plant extrudate, a natural fiber extract, a gelatin, a biosynthetic process starch, a cellulosic material, an alginate, pectin, and combinations thereof.

51. The method of claim 50 wherein the natural gum comprises a gum selected from the group consisting of natural seed gum, guar gum, locust gum, tara gum, gum arabic, ghatti gum, agar gum, and xanthan gum.

52. The method of claim 50 wherein the alginate comprises sodium alginate or calcium alginate.

53. The method of claim 50 wherein the natural seaweed comprises a carrageenan.

54. The method of claim 46 wherein the filler comprises a food-grade bulk filler selected from the group consisting of microcrystalline cellulose, a cellulose polymer, magnesium carbonate, calcium carbonate, ground limestone, a silicate, clay, talc, titanium dioxide, a calcium phosphate, and combinations thereof.

55. The method of claim 54 wherein the cellulose polymer comprises wood.

56. The method of claim 54 wherein the silicate comprises magnesium or aluminum silicate.

57. The method of claim 54 wherein the calcium phosphate comprises mono-calcium phosphate, di-calcium phosphate, or tri-calcium phosphate.

58. The method of claim 42 wherein the edible film further comprises one or more of a medicament, a softening agent, a coloring agent, a flavoring agent, and an emulsifying agent.

59. The method of claim 42 wherein the edible film delivers at least about 0.1wt% cinnamaldehyde to the oral cavity.

60. The method of claim 42 wherein the edible film delivers at least about 0.01wt% cinnamaldehyde to the oral cavity.

61. The method of claim 42 wherein the edible film delivers at least about 0.005wt% cinnamaldehyde to the oral cavity.

62. A method of making a pullulan-free edible film comprising:

- (a) forming an aqueous solution that includes a maltodextrin, a hydrocolloid, and a filler;
- (b) adding an effective amount of an antimicrobial agent to the aqueous solution, wherein the antimicrobial agent comprises cinnamaldehyde; and
- (c) drying the aqueous solution to form a dry edible film.

63. The method of claim 62 wherein adding an effective amount of an antimicrobial agent comprises adding sufficient cinnamaldehyde such that the dry edible film comprises at least about 1 wt% cinnamaldehyde.

64. The method of claim 62 wherein adding an anti-microbial agent comprises adding sufficient cinnamaldehyde such that the dry edible film comprises about 1 wt.% to about 25 wt.% cinnamaldehyde.

65. The method of claim 62 wherein forming an aqueous solution comprises adding sufficient maltodextrine such that the dry edible film comprises about 5 wt.% to about 60 wt.% maltodextrine.

66. The method of claim 62 wherein forming an aqueous solution comprises adding sufficient hydrocolloid such that the dry edible film comprises about 10 wt.% to about 50 wt.% hydrocolloid.

67. The method of claim 62 wherein forming an aqueous solution comprises adding sufficient filler such that the dry edible film comprises about 5 wt.% to about 30 wt.% filler.

68. The method of claim 62 wherein forming an aqueous solution further comprises adding one or more of a medicament, a softening agent, a coloring agent, a flavoring agent, and an emulsifying agent.

69. The method of claim 62 further comprising heating the aqueous solution to a temperature of about 40°C to about 60°C prior to drying the aqueous solution.

70. A treatment method for reducing the number or activity of bacteria in the oral cavity comprising the steps of:

- (a) providing an edible film composition comprising cinnamaldehyde in an amount sufficient to kill or deactivate oral bacteria; and
- (b) causing a person in need of the treatment to consume the edible film composition whereby the bacteria in the oral cavity of the person is reduced or inactivated by the treatment.